

**EPA Registration # 73801-3**

Decision Information for 73801

Decision Seq: 475367
Action Code: R334,NEW PRODUCT;MUP OR END USE PRODUCT WITH UNRE...

Decision Status

Tracking

Create Resubmission

FFS Letters

Waiver Documentation

Action Code History

Secondary Decision

FFS Start Date: 12-Mar-2013
Tentative Ind: No
Start/Stop Clock
FQPA Clock:

Due Date: 12-Feb-2014
75-Day Due Date:
Days Elapsed:

OPP Target Due Date:
21-Day Due Date: 12-Mar-2013
FFS Original Decision: ...

Negotiated Due Date:
90-Day Due Date: 10-Jun-2013

Registrant:
Predecisional Due Date: 29-Jan-2014

Response Due Date:

Current Status: PENDING (20-Feb-2013)

75 Day Letters
45/90 Day Screen
Primary Decisions

FFS Negotiated Due Dates
OPP Target Due Date
Decision Comments
Payment
Unmatched Payments

Decision Ownership
Receipts
Data Package
Reduced Risk
Meetings & Milestones
FFS Information

Receipts	Staff Member	Reg/DCI Number	Submission Due Dt	Response
S:931217	Benbow, Bethany	73801-G	12-Feb-2014	PENDING
New sulfentrazone technical product.				

Viewing Record 1 of 1

73801-62

## Material to be added to an e-Jacket/Jacket

Reg. No. 73801-43

Decision # 475367

Description: New tech product

1. Placement within the e-Jacket/jacket:

- ☒ Default: (chronological, top = newest)  
☐ File Location: (eg. "before page 45 in .pdf")

2. ☒ Send to Data Extraction contractors this material:

- ☒ Newly stamped accepted label 1/29/14  
☐ Notification  
☒ New CSF 2/15/13  
☐ Other: \_\_\_\_\_

3. Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

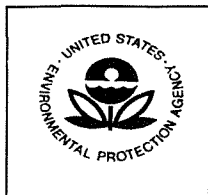
Reviewer: Beth Benbow

Phone: 347-8072

Division: RD

Date: ~~2-10-14~~

2-11-14



**U.S. ENVIRONMENTAL PROTECTION  
AGENCY**

**Office of Pesticide Programs  
Registration Division (7505P)  
Ariel Rios Building  
1200 Pennsylvania Ave., NW  
Washington, D.C. 20460**

EPA Reg.

Number:

**73801-3**

Date of Issuance:

**JAN 29 2014**

**NOTICE OF PESTICIDE:**

☒ Registration

☐ Reregistration

(under FIFRA, as amended)

Term of Issuance: **conditional**

Name of Pesticide Product:

**Sulfentrazone Technical**

Name and Address of Registrant (include ZIP Code):

**Tagros Chemicals India Limited, Ltd  
Jhaver Centre, Rajah Annamalai Building, 4<sup>th</sup> Floor  
72 Marshalls Road, Egmore, Chennai, 600 008, India**

**c/o Biologic, Inc.  
115 Obtuse Hill Road  
Brookfield, CT 06804**

**Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.**

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act. Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is registered in accordance with FIFRA section 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration review/reregistration of your product when the Agency requires all registrants of similar products to submit data. You must comply with the sulfentrazone **DCI ID# GDCI-129081-883** issued on 09/28/2010. If you have questions or concerns regarding registration review, please contact the Chemical Review Manager, Christina Scheltema at (703) 308-2201 or email at [Scheltema.christina@epa.gov](mailto:Scheltema.christina@epa.gov).
2. Make the following label revision(s):
  - a. Revise "EPA Reg. No. 73801-(to be assigned)" to "EPA Reg. No. 73801-3."
  - b. Assure that the EPA establishment number and is also added to the final printed label.
3. Within one year of the date on this registration notice, the Storage Stability (830.6317) and Corrosion Characteristics (830.6320) studies must be submitted. They must be conducted in the commercial containers of this product and observations should be made at 0, 3, 6, 9, and 12 month intervals.
4. Per 40 CFR 156.10(6), submit one copy of your final printed labeling before you release the product for shipment.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec.6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. The basic formulation dated 02/15/2013 is acceptable and will be added to your file. If you have any questions regarding this notice, please contact Beth Benbow of my staff at [benbow.bethany@epa.gov](mailto:benbow.bethany@epa.gov).

Signature of Approving Official:

Kathryn V. Montague  
Project Manager 23  
Herbicide Branch  
Registration Division (7505P)

Date:

**JAN 29 2014**

# SULFENTRAZONE TECHNICAL

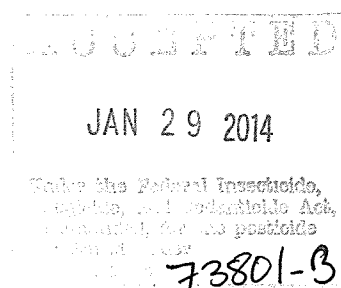
## Herbicide for Formulating Use Only

Active Ingredient:	By Wt
Sulfentrazone: <i>N</i> -{2,4-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1 <i>H</i> -1,2,4-triazol-1-yl]phenyl}methanesulfonamide .....	95.0%
Other Ingredients:.....	5.0%
Total	100.0%

KEEP OUT OF REACH OF CHILDREN

### CAUTION

FIRST AID	
<b>If Inhaled:</b>	Move person to fresh air. If person is not breathing call 911 or an ambulance then give artificial respiration preferably by mouth to mouth if possible. Call a poison control center or doctor for further treatment advice.
<b>If on Skin or Clothing:</b>	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 20 minutes. Call a poison control center or doctor for treatment advice
<b>If in Eyes:</b>	Hold eye open and rinse slowly and gently with water for 15 20 minutes. Remove contact lenses if present after the first 5 minutes then continue rinsing eye. Call a poison control center or doctor for treatment advice.
<b>If Swallowed:</b>	Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.
HOTLINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor or going for treatment. For information on this product, contact the National Pesticide Information Center, 1-800-858-7378, Monday-Friday, 7:30 AM-3:30 PM PST. You may also contact the National Poison Control Center, 1-800-222-1222, day or night, for emergency medical treatment information.	



## **PRECAUTIONARY STATEMENTS**

### **Hazards to Humans and Domestic Animals**

**Caution.** Causes moderate eye irritation. Harmful if swallowed absorbed through skin or inhaled. Avoid contact with skin, eyes or clothing. Avoid breathing vapor. Remove contaminated clothing and wash before reuse. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

### **ENVIRONMENTAL HAZARDS**

Do not discharge effluent containing this product into lakes streams ponds estuaries oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

### **DIRECTIONS FOR USE**

It is a violation of federal law to use this product in a manner inconsistent with its labeling

#### **For Use In Manufacturing Only**

**This material requires further mixing before use.**

**For Formulation Into End Use Herbicide Products For The Following Uses:** Asparagus; Berry Crop Group 13; Brassica head and stem subgroup 5A; Brassica leafy greens subgroup 5B; Cabbage; Citrus Crop Group 10; Dry Bean; Dry Pea; Field Corn; Flax; Horseradish; Melon subgroup 9A; Mint; Vegetable corm and tuberous subgroup 1C; Vegetable fruiting subgroup 8; Okra; Peanuts; Pea, Succulent; Pistachio; Rhubarb; Soybeans; Succulent Cowpea; Succulent Lima Bean; Sugarcane; Sunflower subgroup 20B; Tobacco; Tree Nut Crop Group 14; Turnips; Spring Wheat; Turf; and; Vegetable Soybean (edamame).

## STORAGE AND DISPOSAL

Do not contaminate water food or feed by storage or disposal.

### **Pesticide Storage**

Do not store below 25°C. Product may crystallize at temperatures below 25°C (77°F). In the event that crystallization occurs the material may be melted at temperatures not to exceed 85°C (185°F). Store in original containers only. Store in a dry place and avoid excess heat. Carefully open containers. After partial use replace lids and close tightly. Do not put concentrate or dilute material into food or drink containers

In case of spill avoid contact isolate area and keep out animals and unprotected persons. Confine spills. Call CHEMTREC (Transportation and spills) (800) 424 9300.

To confine spill. Dike surrounding area or absorb with sand cat litter or commercial clay. Place damaged package in a holding container Identify contents.

### **Pesticide Disposal**

Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

### **Container Disposal**

Nonrefillable container. Do not reuse or refill this container. **Metal drum with liner:** Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into formulation equipment. Then offer liner for recycling if available or dispose of liner in a sanitary landfill or by incineration or, if allowed by state and local authorities, by burning. If burned, stay out of smoke. Offer drum for recycling or reconditioning, if appropriate, or puncture and dispose of container in a sanitary landfill, or by other procedures approved by state and local authorities.

## LIMITATION OF WARRANTY AND LIABILITY

**NOTICE:** Read this Limitation of Warranty And Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

It is impossible to eliminate all risks associated with the use of this product. Such risks arise from weather conditions, soil factors, off-target movement, unconventional farming techniques, the presence of other materials, the manner of use or application, or other unknown factors, all of which are beyond the control of Tagros Chemicals India, Ltd. These risks can cause: ineffectiveness of the product, crop injury, or injury to non-target crops or plants.

Tagros Chemicals India, Ltd. does not agree to be an insurer of these risks beyond what is expressly warranted by this label. When you buy or use this product, you agree to accept these risks.

Tagros Chemicals India, Ltd. warrants that this product conforms to the chemical description on the label thereof and is reasonably fit for the purpose stated in the Directions for Use, subject to the inherent risks described above, when used in accordance with the Directions for Use under normal conditions.

To the extent consistent with applicable law, Tagros Chemicals India, Ltd. makes no other express or implied warranty of fitness or of merchantability or any other express or implied warranty.

To the extent consistent with applicable law, in no event shall Tagros Chemicals India, Ltd. or seller be liable for any incidental, consequential, or special damages resulting from the use or handling of this product. Buyer's or user's bargained-for expectation is crop protection. To the extent consistent with applicable law, the exclusive remedy of the user or buyer and the exclusive liability of Tagros Chemicals India, Ltd. or seller, for any and all claims, losses, injuries, or damages (including claims based on breach of warranty or contract, negligence, tort, or strict liability), whether from failure to perform or injury to crops or other plants, and resulting from the use or handling of this product, shall be the return of the purchase price of the product, or at the election of Tagros Chemicals India, Ltd. or seller, the replacement of the product.

To the extent consistent with applicable law that allows such requirement, Tagros Chemicals India, Ltd. or its Retailer must have prompt notice of any claim so that an immediate inspection of buyer's or user's growing crops can be made. Buyer and all users shall promptly notify Tagros Chemicals India, Ltd. or a Tagros Chemicals India, Ltd. Retailer of any claims, whether based on contract, negligence, strict liability, or other tort or otherwise be barred from any remedy.

This Limitation of Warranty And Liability may not be amended by any oral or written agreement.

**EPA Registration No. 73801-(to be assigned)**

**EPA Establishment No. XXXXX-XXX-XXX**

**Net Weight:**

\_\_\_\_\_ 110 lbs. (50 kg)

\_\_\_\_\_ 55 lbs. (25 kg)

**Manufactured by:**

Tagros Chemicals India, Ltd.

Jhaver Centre, Rajah Annamalai Building, 4th Floor,

72 Marshalls Road, Egmore, Chennai, 600 008, India



## Benbow, Bethany

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**From:** Jane Miller [jmill@biologicconsulting.com]  
**Sent:** Wednesday, January 29, 2014 9:21 AM  
**To:** Benbow, Bethany  
**Subject:** RE: EPA D# 475367 (73801-G); label revisions required  
**Attachments:** 73801-G.20140129.Sufentrazone Technical.Label.pdf

Here is the revised label. I made one change in that I added "...or using the toilet" to the end of the "Hazards to Humans..." section. This is what I have been asked to do by other PM's.

Thank you for your help!

Best Regards,

*Jane M. Miller*

BIOLOGIC CONSULTING, INC.

115 Obtuse Hill Road  
Brookfield, CT 06804

Tel: 203-740-1200

Fax: 203-740-1220

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**From:** Benbow, Bethany [mailto:Benbow.Bethany@epa.gov]  
**Sent:** Wednesday, January 29, 2014 8:37 AM  
**To:** jmill@biologicconsulting.com; lmill@biologicconsulting.com  
**Subject:** EPA D# 475367 (73801-G); label revisions required

Good morning,

I am contacting you in regard to the proposed *Sulfentrazone Technical* label submitted on behalf of Tagros Chemicals India, Ltd.

A few revisions are needed in order to have clean labeling:

1. Add, "and before eating, drinking, chewing gum, or using tobacco." to the last sentence of the "Hazards to Humans and Domestic Animals" section.
2. Also in this section, add a comma between "skin" and "eyes" in the second sentence. Add a period after "vapor."
3. In the "Pesticide Storage" section, change the text, "dunk containers" to "drink containers."

You may submit clean labeling as a pdf attachment in response to this email. Please let me know if you have any questions or concerns.

Kind Regards,

Beth

**Bethany Benbow**

Biologist/Risk Manager

Registration Division

Office of Pesticide Programs

**Environmental Protection Agency**



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS  
REGISTRATION DIVISION (7505P)

DATE OUT: 16 / JANUARY / 2014

SUBJECT: **PRODUCT CHEMISTRY REVIEW OF MP [ X ] EP [ ]**  
DP BARCODE No.: DP410638 EPA File Symbol No.: 73801-G  
PRODUCT NAME: Sulfentrazone Technical  
COMPANY: Tagros Chemicals India Ltd.  
FOOD USE [ X ] **INTEGRATED FORMULATION [ X ]**  
PCC: 129081 Decision No. 475367  
ACTION CODE: R334 Pesticidal use: Herbicide

FROM: Hari Mukhoty  
Product Chemistry Team  
Technical Review Branch / RD (7505P)

*ofm.* *8/8*  
*01-17-19*

TO: Bethany Benbow, CRM / Kathryn Montague, RM 23  
Herbicide Branch / RD (7505P)

**INTRODUCTION:**

The Registrant has submitted a basic CSF (dated: 02/15/2013) for a proposed TGA/MP, and has also proposed a product specific label for registration of the aforesaid product under EPA File symbol 73801-G. The product chemistry data have been submitted under MRIDs: 490590-01 and -02.

The application for registration has been submitted by Biologic Inc., an agent for Tagros Chemicals India, Ltd. The technical product is manufactured by Tagros Chemicals India, Ltd. located in Chennai, India. Group A and Group B data have been prepared by Biologic Inc. Connecticut, USA. The five batch analysis was performed by EPL Bio Analytical Services located in Niantic, IL, USA.

Proposed label text indicates that this proposed TGA/MP is intended to be formulated into end-use products with food uses.

TRB has been requested to evaluate the product chemistry data required for the registration of the proposed TGA/MP.

**SUMMARY OF FINDINGS:**

1. The proposed TGA/MP contains the active ingredient: Sulfentrazone (95.00%).
2. The overall mean of the active ingredient from the five batch analysis is 94.883% [MRID: 490590-02, Page 21].

**DP BARCODE No.:** 410638 **EPA File Symbol No.:** 73801-G **PRODUCT NAME:** Sulfentrazone Technical

PRODUCT CHEMISTRY DATA (SERIES 830 Group A)

Group A	Data Required Fulfilled	MRID No.
830.1550. Chemical Identity (same as in Product CSF dated: 02/15/2013)	A	490590--01
830.1600. Beginning Materials	A	"
830.1620. Production process	A	"
830.1650. Formulation process	NA	
830.1670. Discussion of Impurities	A	"
830.1700. Preliminary Analysis	A	490590-02
830.1750. Certified Limits	A	490590-01
830.1800. Enforcement Analytical Method	A	490590-02

A = Acceptable NA = Not Applicable

DP BARCODE No.: 410638 EPA File Symbol No.: 73801-G PRODUCT NAME: Sulfentrazone Technical

Table 2: Physical and Chemical Properties of: Sulfentrazone Technical				
GLN	Requirement	MRID	Status	Result or Deficiency
830.6302	Color	490590-02	A	Tan
830.6303	Physical state	"	A	Solid Powder
830.6304	Odor	"	A	Odorless
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	"	A	Stable for 14 days to normal and elevated (54°C) temperatures
830.6314	Oxidation/reduction: chemical incompatibility	"	A	Does not react vehemently with water, $\text{NH}_4\text{H}_2\text{PO}_4$ , iron powder, kerosene, and $\text{KMnO}_4$ solution
830.6315	Flammability	Data matrix	A	Not applicable. It is solid and is not expected to be flammable
830.6316	Explosibility	Data Matrix	A	Not applicable
830.6317	Storage stability	Data matrix	G	In progress
830.6319	Miscibility	Data matrix	W	Not supposed to be mixed with Petroleum solvents
830.6320	Corrosion characteristics	Data Matrix	G	In progress
830.7000	pH	CSF/490590-02	A	5.64
830.7050	UV/Visible absorption	490590-02	A	In distilled water, 0.1N NaOH and 0.1N HCL a weak absorbance band in the 190-220 nm range was observed.
830.7100	Viscosity	Data Matrix	NA	Because the product is solid.
830.7200	Melting point	490590-02	A	118.8 °C
830.7220	Boiling point	"	NA	Data not applicable because it is a solid
830.7300	Density	490590-02	A	Pour Density 0.266 g/mL / Tap density 0.416 g/ml
830.7370	Dissociation constants in water (DC)	490590-02	A	6.58
830.7550	Partition coefficient	490590-02	A	Log Pow = 1.562
830.7840	Water solubility	490590-02	A	In water 0.373, Methanol 0.065, Hexane 0.017 n-Octanol 3.334 g/L
830.7950	Vapor pressure	Data Matrix	A	Publised Literature $1.3 \times 10^{-7}$ Pa
A = Acceptable; N = unacceptable (see Deficiency); N/A = Not Applicable; G = Data gap; I = In progress ; U = Up-grade (additional information required); W = waivers				









UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND  
POLLUTION PREVENTION

DATE March 26, 2013

**MEMORANDUM**

Subject: EPA File Symbol/Reg. No.: 73801-G

Product Name: Sulfentrazone Technical  
DP Barcode: 410379  
Decision No.: 475367  
Action Code: R334  
PC Code: 129081 Sulfentrazone (95%)

From: John C. Redden, M.S.  
Technical Review Branch (TRB)  
Registration Division (7505P)

SCR  
BA

Through: OPP Similarity Clinic  
Registration Division (7505P)

To: PM 23  
Herbicide Branch (HB)  
Registration Division (7505P)

Applicant: Tagros Chemicals India, Ltd.  
Jhaver Center, R.A. Building, 4<sup>th</sup> Floor  
72 Marshall Road  
Egmore, Chennai, 600 008, India

<u>Active Ingredient</u>	<u>% by weight</u>
Sulfentrazone.....	95%
Inert Ingredients.....	<u>5%</u>
	100.0%



**OPP Similarity Clinic****Date:** March 26 2013

The applicant submitted product chemistry data for EPA File Symbol No. 73801- G. This data will be reviewed by February 12, 2014. The applicant is citing EPA Reg. No. 279-3149.

**Tox Profile:**

The Clinic finds that the proposed product is similar to the cited product. DER's for the five studies are in TXR 0009263.

The purity of the test material used in the acute dermal, primary eye, dermal and dermal sensitization studies was reported in TXR 0009823. Also in this document the acute inhalation requirement was waived and the lack of a positive control study for the dermal sensitization study was addressed.

All of the studies are Core Guideline.

STUDY	MRID No.	Test Material Purity	TOX CAT	Pages
Acute Oral - Rat	41911605	94.0%	3	4-5
Acute Oral - Mouse	41911606	94.0%	3	5-6
Acute Dermal - Rabbit	41911607	92.5%	3	8-9
Primary eye – Rabbit	41911608	92.5%	3	10-11
Primary dermal – Rabbit	41911609	92.5%	4	12-13
Dermal sensitization – Guinea Pig	41911610	92.5%	Neg.	14-16

**PRODUCT ID #:** 073801-0000~~6~~6**PRODUCT NAME:****PRECAUTIONARY STATEMENTS****SIGNAL WORD:** CAUTION**Hazards to Humans and Domestic Animals:**

Harmful if absorbed through skin. Harmful if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Wear long-sleeved shirt and long pants, socks, shoes, and gloves. Remove and wash contaminated clothing before reuse. Avoid contact with eyes or clothing. Wear protective eyewear. Wear: Long-sleeved shirt and long pants, Socks, Shoes, and gloves.

**First Aid:**

If on skin:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

If swallowed:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

If in eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

# Similarity Clinic Screen Completed

Date: 3/27/13

Jacket #: 73801-6

## Actions Done:

Acute Toxicity Review: COMPLETED - IN JACKET  
Acute Toxicity Language for Label: IN REVIEW

Product Chemistry Review: SUBMITTED - SEND TO  
TRB FOR FULL REVIEW

## ~~Transfer This Jacket To:~~

PM 23, KAY MONTAGUE

BETH -

SIMILARITY DETERMINATION  
ALREADY DONE. SEE JACKET.

# Completion of 21-Day Content Screen

PM- 23

EPA Reg. # (File Symbol) 73801-G

Decision # D 475367

Data package delivered to  
you on 2/25/13.  
(date)

Jacket/Mini-jacket will be  
transferred to you today.  
(Pick up from Document Center)

Thank you, *AS*

Registration Division's 21-Day Content Team

**BIOLOGIC** INC.  
*agribusiness professionals*

February 18, 2013

Ms. Kathryn Valente Montague  
 Product Manager, PM Team 23  
 Herbicide Branch (7505P)  
 Registration Division  
 Office of Pesticide Programs  
 U.S. Environmental Protection Agency  
 Ariel Rios Building  
 1200 Pennsylvania Avenue, N.W.  
 Washington, D.C. 20460

SUBJECT: Registration Application for "Sulfentrazone Technical"; EPA File Symbol: 73801-(to be assigned); Tagros Chemicals India, Limited.

Dear Ms. Montague:

With this letter, we are submitting on behalf of Tagros Chemicals India, Limited the above-mentioned registration application for "Sulfentrazone Technical"; EPA File Symbol 73801-(to be assigned). Please note the following enclosed items:

**Administrative Materials:**

- Application for Pesticide Registration (EPA Form 8570-1).
- Data Matrix (EPA Form 8570-35).
- Certification With Respect to Citation of Data (EPA Form 8570-34).
- Confidential Statement of Formula (EPA Form 8570-4).
- Draft Labeling (5 Copies).

**49059001 Product Identity and Composition of Sulfentrazone TGAI:**

- Product Identity and Composition (OPPTS 830.1550).
- Description of Materials Used to Produce the Product (OPPTS 830.1600).
- Description of Production Process (OPPTS 830.1620).
- Discussion of Formation of Impurities (OPPTS 830.1670).
- Certified Limits (OPPTS 830.1750).

**49059002 Determination of the Physical and Chemical Characteristics and Preliminary Analysis of Technical Sulfentrazone:**

- Preliminary Analysis (OPPTS 830.1700).
- Certified Limits (OPPTS 1750).
- Enforcement Analytical Method (OPPTS 830.1800).

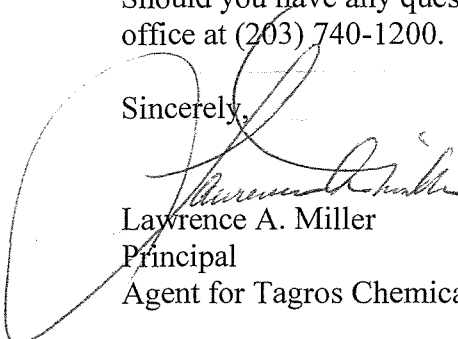
- Color (OPPTS 830.6302).
- Physical State (OPPTS 830.6303).
- Odor (OPPTS 830.6304).
- Stability to Normal and Elevated Temperatures, Metals and Metal Ions (OPPTS 830.6313).
- Oxidation/Reduction: Chemical Incompatibility (OPPTS 830.6314).
- pH (OPPTS 830.7000).
- UV/Visible Absorption (OPPTS 830.7050).
- Melting Point/Melting Range (OPPTS 830.7200).
- Density/Relative Density/Bulk Density (OPPTS 830.7300).
- Dissociation Constants in Water (OPPTS 830.7370).
- *n*-octanol/water Partition Coefficient (OPPTS 830.7550).
- Water Solubility (OPPTS 830.7840).

The applicant requests the Agency review the enclosed data and the proposed labeling in its determination of substantial similarity to "Sulfentrazone Technical"; EPA Registration Number 279-3149.

This application for a new manufacturing use product falls within the EPA PRIA category - Registration Division: New Product, EPA Number R334; CR Number 53. Accordingly, a fee of \$17,993.00 has been paid by the applicant for processing this application with a decision date of eleven (11) months.

Should you have any questions or otherwise wish to reach me, please feel free to contact my office at (203) 740-1200.

Sincerely,



Lawrence A. Miller

Principal

Agent for Tagros Chemicals India, Ltd.

cc: R. Mathew – Tagros Chemicals India, Ltd.



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**401 M Street, S.W.**  
**WASHINGTON, D.C. 20460**

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Do not send the completed form to this address.

**Certification with Respect to Citation of Data**

Applicant's/Registrant's Name, Address, and Telephone Number Tagros Chemicals India, Ltd. c/o Biologic, Inc. 115 Obtuse Hill Road Brookfield, CT 06804	EPA Registration Number/File Symbol 73801-X
Active Ingredient(s) and/or representative test compound(s) Sulfentrazona	Date February 15, 2013
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Terrestrial Food, Terrestrial Non-Food, Domestic Outdoor	Product Name Sulfentrazone Technical

**NOTE:** If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

**SECTION I: METHOD OF DATA SUPPORT** (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

**SECTION II: GENERAL OFFER TO PAY**

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

**SECTION III: CERTIFICATION**

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

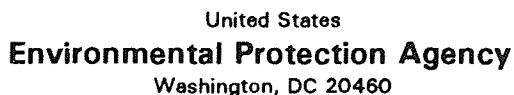
I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature 	Date Feb. 15, 2013	Typed or Printed Name and Title Jane M. Miller, Agent
---------------	-----------------------	--



<input checked="" type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input type="checkbox"/>	Other

OPP Identifier Number

## Application for Pesticide - Section I

1. Company/Product Number 73801-X	2. EPA Product Manager K. Montague	3. Proposed Classification  <input checked="checked" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Sulfentrazone Technical	PM# 23	
5. Name and Address of Applicant <i>(Include ZIP Code)</i>  Tagros Chemicals India Limited c/o Biologic, Inc. 115 Obtuse Hill Road Brookfield, CT 06804  <input type="checkbox"/> Check if this is a new address		6. <b>Expedited Review.</b> In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. <u>279-3149</u>  Product Name <u>Sulfentrazone Technical</u>

## Section - III

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

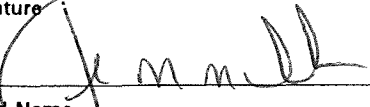
**Explanation:** Use additional page(s) if necessary. (For section I and Section II.)

This is an application for a new MUP which falls under the classification - Registration Division: New Product, EPA No. R334; CR No. 53. The PRIA fee for this application is \$17,993.

### Section - III

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input checked="" type="checkbox"/> Other (Specify) <u>LDPE lined drum</u>
	If "Yes" Unit Packaging wgt.      No. per container	If "Yes" Package wgt      No. per container	
* <b>Certification must be submitted</b>			
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 55 - 110 lbs.	5. Location of Label Directions <input checked="" type="checkbox"/> on label
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____	

## Section - IV

<b>1. Contact Point</b> <i>(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)</i>		
<b>Name</b> Jane M. Miller	<b>Title</b> Agent	<b>Telephone No. (Include Area Code)</b> 203-740-1200
<b>Certification</b>  I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		<b>6. Date Application Received (Stamped)</b>               <div style="text-align: right; font-size: 2em;">24</div>
<b>2. Signature</b> 	<b>3. Title</b> Agent	
<b>4. Typed Name</b> Jane M. Miller	<b>5. Date</b> February 15, 2013	



**From:** paygovadmin@mail.doc.twai.gov  
**Sent:** Monday, February 18, 2013 12:12 PM  
**To:** jmill@biologicconsulting.com  
**Subject:** Pay.gov Payment Confirmation: PRIA Service Fees

Application Name: PRIA Service Fees  
Pay.gov Tracking ID: 259L0490  
Agency Tracking ID: 74412200249  
Transaction Type: Sale  
Transaction Date: Feb 18, 2013 12:11:46 PM

Decision Number:  
Registration Number:  
Company Name: Tagros Chemicals India Lt Company Number: 73801 Action Code: R334


THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

[illegible]

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**DATA MATRIX**

Date February 15, 2013			EPA Reg. No./File Symbol 73801-X		Page 1 of 5
Applicant's/Registrant's Name & Address			Product:		
Tagros Chemicals India, Ltd. c/o Biologic, Inc. 115 Obtuse Hill Road Brookfield, CT 06804			Sulfentrazone Technical		
Ingredient Sulfentrazone					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830-1550	Product Identity and Composition		TAGROS CHEMICALS INDIA, LTD.	Own	
830.1600	Description of Materials Used to Produce the Product		TAGROS CHEMICALS INDIA, LTD.	Own	
830.1620	Description of Production Process		TAGROS CHEMICALS INDIA, LTD.	Own	
830-1650	Description of Formulation Process				1
830.1670	Discussion of Formation of Impurities		TAGROS CHEMICALS INDIA, LTD.	Own	
830.1700	Preliminary Analysis		TAGROS CHEMICALS INDIA, LTD.	Own	
830.1750	Certified Limits		TAGROS CHEMICALS INDIA, LTD.	Own	
830.1800	Enforcement Analytical Method		TAGROS CHEMICALS INDIA, LTD.	Own	
830.1900	Submittal of Samples				2
830.6302	Color		TAGROS CHEMICALS INDIA, LTD.	Own	
830.6303	Physical State		TAGROS CHEMICALS INDIA, LTD.	Own	
830.6304	Odor		TAGROS CHEMICALS INDIA, LTD.	Own	
830.6313	Stability to normal & elevated temp., metal, metal ion		TAGROS CHEMICALS INDIA, LTD.	Own	
830.6314	Oxidation/Reduction		TAGROS CHEMICALS INDIA, LTD.	Own	
830.6315	Flammability / Flame Extension				3
830.6316	Explosibility				4
Signature 			Name and Title		Date
			Jane M. Miller, Agent		02/15/13


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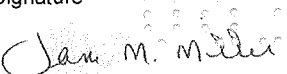
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Ingredient Sulfentrazone					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6317	Storage Stability				5
830.6319	Miscibility				6
830.6320	Corrosion Characteristics				7
830.6321	Dielectric Breakdown Voltage				8
830.7000	pH		TAGROS CHEMICALS INDIA, LTD.	Own	
830.7050	UV/Visible Spectrum		TAGROS CHEMICALS INDIA, LTD.	Own	
830.7100	Viscosity				9
830.7200	Melting Point/ Melting Range		TAGROS CHEMICALS INDIA, LTD.	Own	
830.7300	Density		TAGROS CHEMICALS INDIA, LTD.	Own	
830.7370	Dissociation Constant		TAGROS CHEMICALS INDIA, LTD.	Own	
830.7550	Octanol/Water Partition Coefficient		TAGROS CHEMICALS INDIA, LTD.	Own	
830.7840/60	Water Solubility		TAGROS CHEMICALS INDIA, LTD.	Own	
830.7950	Vapor Pressure				10
Signature			Name and Title		Date
			Jane M. Miller, Agent		02/15/13
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Tagros Chemicals India, Ltd. c/o Biologic, Inc. 115 Obtuse Hill Road Brookfield, CT 06804			Sulfentrazone Technical		
Ingredient Sulfentrazone					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Remaining data requirements including Acute Toxicity, Ecological Effects, Environmental Fate, Residue and all other generic data requirements, including task forces.	CITE-ALL		FMC Corporation	Pay	
			Philadelphia, PA		
			E.I. Du Pont De Nemours and Co.	Pay	
			Wilmington, DE		
			PBI/Gordon Corp.	Pay	
			Kansas City, MO		
			Chemsico	Pay	
			St. Louis, MO		
			Spray Drift Task Force	Pay	
			Washington, DC		
			Agricultural Reentry Task Force	Pay	
			Washington, DC		
Signature 			Name and Title		Date
			Jane M. Miller, Agent		02/15/13

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## DATA MATRIX

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29


## DATA MATRIX FOOTNOTES

1. **Description of Formulation Process:** Not applicable because the product is a TGAI/MP.
2. **Submittal of Samples:** Not required at this time.
3. **Flammability / Flame Extension:** Not applicable. Product does not contain combustible liquids.
4. **Explodability:** Not applicable. Product is not potentially explosive.
5. **Storage Stability:** In progress.
6. **Miscibility:** Not applicable. Product is not intended for dilution with petroleum solvents.
7. **Corrosion Characteristics:** In Progress.
8. **Dielectric Breakdown Voltage:** Not applicable. Product is not intended for use around electrical equipment.
9. **Viscosity:** Not required because product is a solid.
10. **Vapor Pressure:** According to the EPA guideline for vapor pressure, it is not necessary to perform this test if the vapor pressure is below  $10^{-5}$  Pa. Based on published literature, the vapor pressure for sulfentrazone is  $1.3 \times 10^{-7}$  Pa.

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Date February 15, 2013			EPA Reg. No./File Symbol 73801-X		Page 1 of 5
Applicant's/Registrant's Name & Address			Product		
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Ingredient Sulfentrazone					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			TAGROS CHEMICALS INDIA, LTD.	Own	
			TAGROS CHEMICALS INDIA, LTD.	Own	
			TAGROS CHEMICALS INDIA, LTD.	Own	
					1
			TAGROS CHEMICALS INDIA, LTD.	Own	
			TAGROS CHEMICALS INDIA, LTD.	Own	
			TAGROS CHEMICALS INDIA, LTD.	Own	
			TAGROS CHEMICALS INDIA, LTD.	Own	
					2
			TAGROS CHEMICALS INDIA, LTD.	Own	
			TAGROS CHEMICALS INDIA, LTD.	Own	
			TAGROS CHEMICALS INDIA, LTD.	Own	
			TAGROS CHEMICALS INDIA, LTD.	Own	
			TAGROS CHEMICALS INDIA, LTD.	Own	
					3
					4
Signature			Name and Title		Date
			Jane M. Miller, Agent		02/15/13


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**DATA MATRIX**


Date February 15, 2013			EPA Reg. No./File Symbol 73801-X		Page 2 of 5
Applicant's/Registrant's Name & Address			Product		
Tagros Chemicals India, Ltd. c/o Biologic, Inc. 115 Obtuse Hill Road Brookfield, CT 06804			Sulfentrazone Technical		
Ingredient Sulfentrazone					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
					5
					6
					7
					8
			TAGROS CHEMICALS INDIA, LTD.	Own	
			TAGROS CHEMICALS INDIA, LTD.	Own	
					9
			TAGROS CHEMICALS INDIA, LTD.	Own	
			TAGROS CHEMICALS INDIA, LTD.	Own	
			TAGROS CHEMICALS INDIA, LTD.	Own	
			TAGROS CHEMICALS INDIA, LTD.	Own	
			TAGROS CHEMICALS INDIA, LTD.	Own	
					10
Signature			Name and Title		Date
			Jane M. Miller, Agent		02/15/13
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Date February 15, 2013			EPA Reg. No./File Symbol 73801-X		Page 3 of 5
Applicant's/Registrant's Name & Address			Product		
Tagros Chemicals India, Ltd. c/o Biologic, Inc. 115 Obtuse Hill Road Brookfield, CT 06804			Sulfentrazone Technical		
Ingredient Sulfentrazone					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			FMC Corporation	Pay	
			Philadelphia, PA		
			E.I. Du Pont De Nemours and Co.	Pay	
			Wilmington, DE		
			PBI/Gordon Corp.	Pay	
			Kansas City, MO		
			Chemsico	Pay	
			St. Louis, MO		
			Spray Drift Task Force	Pay	
			Washington, DC		
			Agricultural Reentry Task Force	Pay	
			Washington, DC		
Signature			Name and Title		Date
			Jane M. Miller, Agent		02/15/13
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## DATA MATRIX

[illegible]

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

February 21, 2013

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

BIOLOGIC, INC.  
TAGROS CHEMICALS INDIA LTD.  
115 OBTUSE HILL ROAD  
BROOKFIELD, CT 06804

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 19-FEB-13. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

February 20, 2013

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

OPP Decision Number: D-475367  
EPA File Symbol or Registration Number: 73801-G  
Product Name: SULFENTRAZONE TECHNICAL  
EPA Receipt Date: 19-Feb-2013  
EPA Company Number: 73801  
Company Name: TAGROS CHEMICALS INDIA LTD.

LAWRENCE A. MILLER  
BIOLOGIC, INC.  
TAGROS CHEMICALS INDIA LTD.  
115 OBTUSE HILL ROAD  
BROOKFIELD, CT 06804-

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R334

NEW PRODUCT;MUP OR END USE PRODUCT WITH UNREGISTERED SOURCE OF  
THE ACTIVE INGREDIENT;REQUIRES SCIENCE DATA REVIEW;NEW PHYSICAL  
FORM;SELECTIVE DATA CITATION;

No additional payment is due at this time. If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely,

A handwritten signature in black ink, appearing to be "M. J. He".

Front End Processing Staff  
Information Technology & Resources Management Division

# Fee for Service

{931217E~

This package includes the following

- ☒ New Registration
- ☐ Amendment

☒ Studies? ☐ Fee Waiver?  
☐ volpay % Reduction: \_\_\_\_

for Division

- ☐ AD
- ☐ BPPD
- ☒ RD

Risk Mgr. 23

Receipt No.

S-

931217

EPA File Symbol/Reg. No.

73801-G

Pin-Punch Date:

2/19/2013

☐ This item is NOT subject to FFS action.

## Action Code:

Requested:

R334

Granted:

R334

Amount Due: \$ 17,993.00

## Parent/Child Decisions:

☒ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: W. L. H. S.

Date: 2/20/13

Remarks:

Sum clinic  
acting 279-3149  
for Ca. tax

Receipt for Section 3

S: 931217

Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☒ Yes ☐ No

Application Type: New Registration

Billable: ☒ Yes ☐ No

Company: 73801 TAGROS CHEMICALS INDIA LTD.

V

Risk Manager: Registration Division, Risk Management Team 23

Product #: 73801-G

Product Name: SULFENTRAZONE TECHNICAL

Override#:

Me Too Section3: 279-3149

Me Too Product Name: SULFENTRAZONE TECHNICAL

Application Date: 15-Feb-2013

OPP Rec'vd Date: 19-Feb-2013

Front End Date: 19-Feb-2013

Risk Manager Send Date:

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:  
NEW REGISTRATION WITH STUDIES

New Ingredient Request Date:

New Ingredient Received Date:

Form A: ☐ Signature Date:

Form B: ☐ Signature Date:

Print Letter

Enter More Information

Tracking

Receipt Content

Study

CSF

View/Edit

**21-Day Screen Completed by**  
**Contractor**

**21-Day Expires on** 3-12-13

**Jacket #** 73801-G

**MRID#** 490590

**Content Screen:** Recommend to Pass/Fail

**11-3 Review:** Pass/Fail/NA

**Overall Status:** Recommend to Pass/Fail

**Transfer This Jacket to:**

STEPHEN SCETASCE

# PRIA 2 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

21 Day Screen Start Date: 2-19-13 <sup>3/23/09</sup>  
 Experts In-Processing Signature: B.A. Date 2-21-13 Fee Paid: Yes ☒  
 Division management contacted on issues No ☐ Yes ☐ Date \_\_\_\_\_

EPA Reg. Number: <u>73801-G</u>		EPA Receipt Date: <u>2-19-13</u>				
Items for Review				Yes	No	N/A*
1	<b>Application Form</b> (EPA Form 8570-1)(link to form) signed & complete including package type			X		
2	<b>Confidential Statement of Formula</b> all boxes completed, form signed, and dated (EPA Form 8570-4) (Link to form) a) All inerts (link to <a href="http://www.epa.gov/oppr001/inerts/">http://www.epa.gov/oppr001/inerts/</a> ), including fragrances, approved for the proposed uses (see Footnote A) <i>Tech &amp; Impurities only</i>			X		
		yes	no			
3	<b>Certification with Respect to Citation of Data</b> (EPA Form 8570-34) (Link to form) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)			yes	no	
	If applicable, is there a letter of Authorization for exclusive use only.					
4	<b>Formulator's Exemption Statement</b> (EPA Form 8570-27) (Link to form) completed and signed (N/A if source is unregistered or applicant owns the technical)					X
5	<b>Data Matrix</b> (EPA Form 8570-35) (Link to form) both internal and external copies (PR 98-5) (Link to PR 98-5) completed and signed (N/A if 100% repack) a) Selective Method (Fee category experts use) b) Cite-All (Fee category experts use) c) Applicant owns all data (Fee category experts use)			X		
		yes	no			
		X				
6	<b>5 Copies of Label</b> (link to <a href="http://www.epa.gov/oppfead1/labeling/lrm/">http://www.epa.gov/oppfead1/labeling/lrm/</a> ) (Electronic labels on CD are encouraged and guidance is available)( link to <a href="http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels">http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels</a> )			X		



7	Is the data package consistent with PR Notice 86-5 (link to PRN 86-5)	X		
8	Notice of Filing (link to <a href="http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm">http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm</a> ) included with petitions (link to <a href="http://www.epa.gov/pesticides/regulating/tolerances.htm">http://www.epa.gov/pesticides/regulating/tolerances.htm</a> )			X
9	If applicable for conventional applications, reduced risk rationale (link to <a href="http://www.epa.gov/opprd001/workplan/reducedrisk.html">http://www.epa.gov/opprd001/workplan/reducedrisk.html</a> )			X
10	Required Data (link to <a href="http://www.epa.gov/pesticides/regulating/data_requirements.htm">http://www.epa.gov/pesticides/regulating/data_requirements.htm</a> ) and/or data waivers. See Footnote C.			
	a) List study (or studies) not included with application			

## Comments:

Technical : Impurities only, no inerts to review.

Passed 11-3 review, MRID 490590

JD 2/22/13

\* N/A – Not Applicable

## Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses. If an unapproved inert is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses **even if a product is currently registered** by consulting the inert Web

site [link to <http://www.epa.gov/opprd001/inerts/lists.html>] and if the inert is not approved, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient.** Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at [inertsbranch@epa.gov](mailto:inertsbranch@epa.gov) and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch [Link to [http://www.epa.gov/oppbppd1/biopesticides/contacts\\_bppd.htm](http://www.epa.gov/oppbppd1/biopesticides/contacts_bppd.htm)].

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information [link to <http://www.epa.gov/opprd001/inerts/tips.pdf>] must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

### **Unapproved Inerts Identified on CSFs**

#### **All applications except conventional new products and PIPs**

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

#### Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R311, R312 or R313), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

#### PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

## Memorandum

Date: 02 / 22 / 13

To: PM 23, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

**We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.**

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a:

- ☒ fully accepted submission
- ☐ partially accepted submission
- ☐ rejected submission

FOR OFFICIAL USE ONLY

FILE SYMBOL

REGISTRATION NO.

73801-G

## CONFIDENTIAL STATEMENT OF FORMULA ENCLOSED

DATE SUBMITTED	SUBMITTED BY (✓)	
	APPLICANT	BASIC SUPPLIER
02/19/13		

**Do Not Write Comments,  
Formula, or Parts of Formula  
on This Envelope**

### NOTE

It shall be unlawful—for any person to use for his own advantage or to reveal, other than to the Secretary, or officials or employees of the United States Department of Agriculture or other Federal agencies, or to the courts in response to a subpoena, or to physicians, and in emergencies to pharmacists and other qualified persons, for use in the preparation of antidotes, in accordance with such directions as the Secretary may prescribe, any information relative to formulas of products acquired by authority of Section 4 of the "Federal Insecticide, Fungicide, and Rodenticide Act."

\*Pages 48 -49 Confidential Statement of Formula may be entitled to confidential treatment\*